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Pointe Magnesium - XB Reagent Set

Intended Use
For the quantitative determination of magnesium in serum using the Yumizen C230 and Yumizen C240 analyzers. For *in vitro* diagnostic use only. **Rx Only.**

Clinical Significance
Magnesium in the body is found primarily in bone with some in soft tissue, blood cells, and serum. Decreased levels have been observed in cases of diabetes, alcoholism, diuretics, hyperthyroidism, hypothyroidism, malabsorption, hyperalimenation, myocardial infarction, congestive heart failure and liver cirrhosis. Increased serum magnesium levels have been found in renal failure, diabetic acidosis, Addison's disease, and vitamin D intoxication.

Method History
Serum magnesium measurement was first introduced in the 1920's with the laborious precipitation procedures of Kramer and Tisdall,[1] Briggs,[2] and Denis.[3]
These were followed by a variety of methods including: complexometric EDTA titration procedures,[4] fluorometric procedures involving chelates of magnesium,[5,6] and a dye absorption method based on the reaction of Titan Yellow with magnesium hydroxide to form a red-colored lake.[7] Each of these procedures suffered from numerous technical difficulties which greatly affected the accuracy and precision of their results. Atomic absorption remains the most accurate method for magnesium determinations. However, this method requires expensive instrumentation and uses large sample volumes which limit its usefulness for pediatric testing.[8]
Most recently, colorimetric dye-complexing methods have been developed and are in popular use. These procedures use such dyes as Calmagite, Eriochrome Black T, Xylidyl Blue (Magon), and methylthymol blue.[9] The present procedure uses the metallochromic dye Xylidyl Blue for a rapid, easy and accurate determination of magnesium in serum.

Principle
Serum magnesium ions react with Xylidyl Blue in alkaline medium to produce a red complex that is measured spectrophotometrically. The intensity of color produced is directly proportional to magnesium concentration. Calcium interference is virtually eliminated by use of EGTA and a surfactant system is included to remove protein interference.

Reagent Composition
When combined the reagent contains: xylidyl blue 0.1mM, EGTA 0.13mM, DMSO 1.4M, Buffer, surfactant, non-reactive stabilizers including potassium cyanide at 0.02% w/v. Caution: Poison/Caustic, Avoid All Contact.

Reagent Preparation
The reagents are ready to use.

Reagent Storage and Stability
The magnesium reagent kit should be stored at room temperature, (15-30˚C) until the posted expiration date.

Do not use if:
1. The reagent fails to achieve established values of fresh control sera.
2. The reagent becomes visibly turbid.

Precautions
This reagent is for *in vitro* diagnostic use only.
Reagents are Poison/Caustic, Avoid All Contact.
All specimens and controls should be handled in accordance with good laboratory practices using appropriate precautions as described in the CDC/NIH Manual, "Biosafety in Microbiological and Biomedical Laboratories," 2nd ed., 1988, HHS Publication No. (CDC) 88-8395.

Specimen Collection and Storage
1. Use fresh, unhemolyzed serum or heparinized plasma.
2. Red cells contain twice the magnesium concentration as serum. A hemolyzed sample would falsely elevate results.[10]
3. Grossly icteric or lipemic specimens should not be used in this method.
4. Specimen collection should be carried out in accordance with CLSI M29-A4.[11] No method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood samples should be considered potentially infectious.

Interferences
1. Hemolyzed, grossly icteric or lipemic specimens are unsuitable for this method.
2. A number of drugs and substances affect the concentration of magnesium. See Young, et al.[12]

Materials Provided
Magnesium (xylidyl blue) reagent R1 and R2

Materials required but not Provided
1. Yumizen C230 / Yumizen C240 Analyzer
2. Yumizen C230 / Yumizen C240 Operation manual
3. Pointe Chemistry Calibrator, catalog number C7506-50
4. Pointe Chemistry control, catalog number C7592-100

Test Parameters

Test:	MG	Chemistry:	Magnesium
Chemistry No.:	226	Print Name:	MG
Reaction Type:	Endpoint	Reaction Direction:	Positive
Pri. Wave:	546 nm	Sec. Wave	670
Decimal.:	0.1	Samp. Type:	Serum
Blank Time:		Reaction Time:	9 10
Unit:	mg/dL	Incubation Time:	3

	Sample Vol.	Aspirated	Diluent		Reagent Vol.	Diluent	
Standard;	3	uL	uL	uL	135	uL	uL
Decreased;		uL	uL	uL	135	uL	uL
Increased;		uL	uL	uL			

Linearity Range (Standard);	0.05-4.5		Linearity Limit:	
Linearity Range (Decreased):			Substrate Depletion:	
Linearity Range (Increased):			Mixed Blank Abs.:	- 40000 40000
R1 Blank Abs.:	- 40000	40000	On-board Stability:	Day (s)
Blank Response	- 40000	40000	Reagent Alarm Limit:	5
Twin Chemistry:				

Prozone Check:		
Q1:	Q2:	Q3:
Q4:	PC:	ABS:

Use Qualitative Result:		
	Range:	Flag:

Slope Offset:			
	Slope	Offset	Unit
	1	0	mg/dL

Pretreatment:			
Pretreat Sample Vol.:	uL	Pretreat Reagent Vol.:	uL

Ref. Range:					
Sample Type:	Gender:	Age Range:	Ref. Range:	Critical Range:	Unit:

Pointe
Magnesium - XB
Reagent Set

Calibration Setup Parameters

Chem: MAG
Calibration Setting
Math Model: Two-Point Linear
Factor: Replicates: 2
Acceptance Limits
Cal Time: 24 hr.
Slope Diff: SD:
Sensitivity: Repeatability: * User Defined
Deter Coeff:
Auto Calib.
☐ Cal Time

Calibrator	Conc.	Pos	Lot No.
Water	0.0	W	
Chem Cal	*	*	

NOTE: When running the Magnesium assay set the Carryover Settings as listed below: Go to Parameters → Carryover

Select MG_R1 in upper column and then select the listed assays on lower column GLU_R1, ALP_R1, ALP_R2, CO2-R1, CK_R1, CK_R2 AND TRIG_R1 – Press OK

Select MG_R2 in upper column and then select the listed assays on lower column GLU_R1, ALP_R1, ALP_R2, CO2-R1, CK_R1, CK_R2 AND TRIG_R1 – Press OK

Calibration

Use an NIST-traceable serum based calibrator. The procedure should be calibrated according to the instrument manufacturer's calibration instructions. If control results are found to be out of range, the procedure should be recalibrated.

Quality Control

The validity of the reaction should be monitored by use of control sera with known normal and abnormal magnesium values. These controls should be run at least with every working shift in which magnesium assays are performed. It is recommended that each laboratory establish its own frequency of control determination. Quality control requirements should be performed in conformance with local, state, and/or Federal regulations or accreditation requirements.

Calculation (Ratiometric Calculation) (Example)

Abs. = Absorbance

$$\frac{\text{Abs. of Unknown}}{\text{Abs. of Standard}} \times \text{Conc. of Standard} = \text{Value mg/dl}$$

Example: Abs. of Unknown = .140
Abs. of Standard = .120
Conc. of Standard = 2.4 mg/dl

Then: $\frac{.140}{.120} \times 2.4 \text{ mg/dl} = 2.8 \text{ mg/dl}$

NOTE: "mg/dl" may be converted to "mEq/L" by dividing the result by 1.21525.

Expected Values

Newborns	1.8 - 2.8 mg/dl
Children	1.7 – 2.3 mg/dl
Adults	1.6 – 3.0 mg/dl

The expected values were taken from literature.[13] Each laboratory should establish its own normal range.

Performance

Linearity: 0.05 - 4.5 mg/dl

Comparison: A study was performed between the Yumizen 200 series analyzers and a similar analyzer using this method, resulting in a correlation coefficient of correlation of 0.983 with a regression equation of y=0.945x + 0.05. (N=36).

Precision: Precision studies were performed using the Yumizen 200 series analyzers following a modification of the guidelines which are contained in NCCLS document EP5-T2.[14]

Within Day (N=20)			Day to Day (N=22)*		
Mean	**S.D.**	**C.V.%**	**Mean**	**S.D.**	**C.V.%**
1.91	0.03	1.6	2.9	0.24	8.28
4.37	0.06	1.3	5.2	0.30	5.77

*Note: Day to Day precision does not reflect Yumizen 200 series analyzers performance.

References

1. Kramer, B. Tisdall, F.F., J. Biol. Chem. 47:475 (1921).
2. Briggs, A.P., J. Biol. Chem. 52:349 (1922).
3. Denis, W., J. Biol. Chem. 52:411 (1922).
4. Schwartzenbach, G., et al, Helvet Chim. Acta 29:811 (1946).
5. Schachter, D., J. Lab. and Clin. Med. 54:763 (1959).
6. Brien, M., Marshall, R.T., J. Lab. and Clin. Med. 68:701 (1966).
7. Basinski, D.H., Standard Methods of Clinical Chemistry, 5, New York, Academic Press, pp. 137-142 (1965).
8. Natelson, S., Techniques of Clinical Chemistry, 3rd Ed., Springfield (Ill.), C.C., Thomas, pp. 190-197(1971).
9. Korbl, J., Pribl, R., Chem. Listy 51:1061 (1957) and Anal. Abst. 5:10 (1958).
10. Tietz, N.W., Fundamentals of Clinical Chemistry, Philadelphia, W.B. Saunders, p. 918 (1976).
11. CLSI M29-A4 "Protection of Laboratory Workers From Occupationally Acquired Infections", 4th Ed. (2014).
12. Young, D.S., et al, Clin. Chem. 21:1D (1975).
13. Bagniski, E.S., et al, Selected Methods of Clinical Chemistry, Vol. 9, Washington (DC), AACC, pp. 227-281 (1982).
14. NCCLS document "Evaluation of Precision Performance of Clinical Chemistry Devices", 2nd Ed. (1992).

Symbol Key

Use by (YYYY-MM-DD)	LOT Lot and batch code
REF Catalog number	Manufacturer
IVD *In vitro* diagnostic medical device	Temperature limitation
Consult instructions for use	**Rx Only:** Prescription Use Only
CE mark	EC REP Authorized representative in the European Community

REF 12-HM729-160 Manufactured by HORIBA Instruments Incorporated - Pointe Brand 5449 Research Drive Canton, MI 48188 IVD

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Certified to Perform Reagents

The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

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